



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

is re application of

Wolfgang HEIL et al.

Serial No.: 09/757,688

Filed: January 11, 2001

For: DROSPIRENONE FOR HORMONE REPLACEMENT THERAPY

Group Art Unit: Unknown

Examiner: Unassigned

SUPPLEMENTAL PRELIMINARY AMENDMENT

Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

Further to our Preliminary Amendment filed February 23, 2001, please amend the above-identified application as follows:

In the Claims:

Please revise claims 77, 81, 89, and 94 as follows:

77. (Amended) A pharmaceutical composition comprising

as a first active agent, an estrogen (or naturally or synthetic derivative thereof) in sufficient amounts to treat diseases, disorders and symptoms associated with deficient endogenous levels of estrogen in women, and

as a second active agent,  $6\beta,7\beta;15\beta,16\beta$ -dimethylene-3-oxo- $17\alpha$ -preg-4-ene-21,17-carbolactone (drospirenone) in sufficient amounts to protect the endometrium from the adverse effects of estrogen,

together with a pharmaceutically acceptable excipient or carrier.

81. (Amended) A composition according to claim 77, wherein the estrogen is selected from the